

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1 and 5 are canceled. Claims 2-4, 6 and 21 are currently being amended. Claims 7-20 are withdrawn.

Upon entry of the foregoing amendments, Claims 2-4, 6 and 21 are pending.

### **I. Rejections under 35 U.S.C. § 112, first paragraph**

Claims 4 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description of an HBV-like particle comprising precore protein. See Office Action, page 3. Applicants respectfully traverse this basis for rejection.

The Examiner maintains this rejection because “neither Sakamoto nor the cited specification teaches an HBV virus-like particle comprising precore protein.” See Office Action, page 4. Regarding claim 4, the Examiner also alleges that this claim does not meet the enablement requirement because “[o]ne of ordinary skill in the art would not know how to make it from the disclosure.” See Office Action page 5.

Sakamoto *et al.*, page 681, Figure 1a and Table 1, shows that there are many particles which are HBV-like particles containing DNA that are not HBV core particles. It is not described that the particles are formed from precore protein. This is because, at the time of Sakamoto’s publication, it was widely considered that HBV particles are formed from HBV-core.

Also, the present specification does disclose HBV particles formed from precore protein. Specifically, Figure 3 shows a small peak of HBsAg within fractions 23 and 24. In addition, fractions 23 and 24 in Figure 4 display maintenance of particle structure following treatment with NP-40. This means that the HBV particles present in those fractions were formed from precore protein and not from HBV core and DNA.

A person of ordinary skill in the art would be able to obtain these HBV particles formed from precore protein, which do not contain HBV core and DNA, by the methods described in Examples 3 and 4 of the specification.

Thus, claim 4 meets the written description requirement and claims 3, 4 and 6 are enabled. Therefore, Applicants respectfully request withdrawal of this basis for rejection.

## **II. Rejection under 35 U.S.C. § 102(b)**

Claims 21 is rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Takahashi *et al.*, *J. Immunology* 147(9):3156-3160 (1991) (“Takahashi”). See Office Action, page 6. Applicants respectfully traverse the rejection.

Claim 21 has been amended to describe a **specific** antibody. Takahashi does not describe a specific antibody. Therefore, Takahashi does not anticipate claim 21.

Therefore, Applicants respectfully request withdrawal of this basis for rejection.

## **III. Rejections under 35 U.S.C. § 103(a)**

Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being allegedly obvious over Takahashi, set forth *supra*, and Kobayashi *et al.*, *Gene* 30:227-232 (1984) (“Kobayashi”). The Examiner acknowledges that Takahashi fails to teach the claimed SEQ ID NO.: 1. See Office Action of December 14, 2007, page 11. The Examiner, however, alleges that Kobayashi in combination with Takahashi render the instant claims obvious. *Id.* Applicants respectfully traverse this basis for rejection.

As described above, claim 1 is now canceled.

As the Examiner pointed out, Takahashi describes HBV precore products comprising p21c, p20, p18 and p17. Among these four disclosed precore products described by Takahashi, only one (p21c) has a particle form. According to the Takahashi reference, although p21c reacts with a monoclonal antibody (2212) which recognized the C-terminus (amino acids 150-183) of HBcAg, the precore protein of the present invention does not react with HB50, an antibody that recognizes the HBcAg C-terminus. Therefore, the present

precure protein and the p21c described in Takahashi are different within their C-termini. Thus, Takahashi does not teach or suggest the current invention. This deficiency is not overcome by Kobayashi, which simply discloses an amino acid sequence related to, but not identical to, the claimed sequence.

Therefore, Applicants respectfully request withdrawal of this basis for rejection.

## **VII. Conclusion**

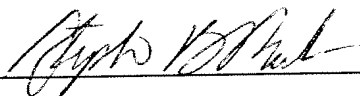
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5569  
Facsimile: (202) 672-5399

Stephen B. Maebius  
Attorney for Applicant  
Registration No. 35,264